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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,537	04/16/2001	Carl R. Merrill	PNC-004	5407
61223 7590 01/22/2007 PANACEA PHARMACEUTICALS, INC. 207 PERRY PARKWAY SUITE 2 GAITHERSBURG, MD 20877			EXAMINER PRYOR, ALTON NATHANIEL	
			ART UNIT	PAPER NUMBER
			1616	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/22/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

09/835,537

Applicant(s)

MERRIL ET AL.

Examiner

Alton N. Pryor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 29 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 19 and 21-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 19 and 21-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

- I. Rejection of claims 19,21-35 under 35 USC 112, 1<sup>st</sup> paragraph and rejection of claims 19,22-25,27-29 under 35 USC 102(e) and 103(a) as being anticipated by / obvious over Kaddurah-Daouk will be maintained in light of amendment filed 11/27/06 for reason on record and reason as follows. Applicant argues that no structure for guanidine acetate exists. Examiner argues the claims comprise a guanidine salt, which would include guanidinoacetate. Guanidinoacetate is assumed to be guanidine acetate absent a showing that the structures differ. For this reason the rejections on record are maintained.
- II. Rejection of claims 30 and 32 under 35 USC 112, 2<sup>nd</sup> paragraph will not be maintained in light of amendment filed 11/27/06. Note claims 30 and 32 have been amended to recite guanidine HCl and KI respectively.
- III. Objection to claims 23 and 27 will not be maintained in light of amendment filed 11/29/06. Claim 23 now depends from claim 19, and claim 27 has been amended by inserting --- or --- after CJD in line 2 of claim 27.
- IV. Rejection of claims 19,23-29,31 under 35 USC 102(b) and 103(a) as being anticipated by and obvious over Azumendi in light of amendment filed 11/27/06 will be maintained for reason on record and reason as follows.  
  
Applicant argues that Azumendi
  - a) teaches treating prion diseases in mammals by administering NaI or KI to the mammals. (The aspect of hyperthermia being induced by NaI or KI is

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not understood). Hyperthermia is an optional component of treatment in accordance with the present invention; and

- b) cannot be interpreted as disclosing a method for treating prion diseases (BSE or CJD) by administering Nal or KI (Azumendi speculates the treatment will be effective against BSE and CJD).

Examiner argues that

- c) both Azumendi and instant invention discloses the same active step, i.e., administering chaotrophic agents (KI or Nal) to mammals. Therefore since both inventions disclose identical active step, it is inherent that both inventions would induce hyperthermia; and
- d) Azumendi clearly expresses that KI or Nal is administered to mammals to treat prion diseases such as BSE or CJD. See abstract, page 5 lines 17-20, claim 1.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

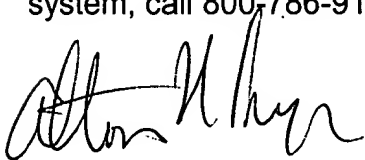
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***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Alton N. Pryor', is written over the printed name and title.

Alton Pryor  
Primary Examiner  
AU 1616